

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

25 FEB 2005

Applicant's or agent's file reference 15228-15pct	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/CA 03/01248	International filing date (day/month/year) 25.08.2003	Priority date (day/month/year) 26.08.2002
International Patent Classification (IPC) or both national classification and IPC A61B19/00		
Applicant ORTHOSOFT INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand

05.12.2003

Date of completion of this report

26.11.2004

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International application No. **PCT/CA 03/01248**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

Description, Pages

1-14 as originally filed

Claims, Numbers

5-22 as originally filed
1-4, 23-26 received on 26.10.2004 with letter of 26.10.2004

Drawings, Sheets

1/6-6/6 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).
- (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
 - ☒ claims Nos. 14-24
- because:
- ☒ the said international application, or the said claims Nos. 14-24 relate to the following subject matter which does not require an international preliminary examination (specify):
- see separate sheet**
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - ☐ no international search report has been established for the said claims Nos.
2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:
- ☐ the written form has not been furnished or does not comply with the Standard.
 - ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-13, 25, 26
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-13, 25, 26
Industrial applicability (IA)	Yes: Claims	1-13, 25, 26
	No: Claims	

2. Citations and explanations

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see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 14-24 relate to a method for treatment of the human or animal body by surgery, in particular the step: "placing said at least two spinal implants" (claim 14, line 20).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-13, 25 and 26 does not involve an inventive step in the sense of Article 33(3) PCT.

1.1 Document **DE-A-10057023 (D1)** already discloses (see abstract; col. 4, lines 25-55; Fig. 1):

An apparatus for planning a surgery, comprising:

a display 13 for an image representing a patient's anatomy;

a database of virtual bone fragments (see col. 4, lines 45-55);

a tool for a user to manipulate and place said bone fragments in said image at desired locations; and

a positioning module 12 (implicitly present in the computer of D1, since the position of the bone fragments can be rearranged to fit a preferred outline ("sollposition") M1) adapted to calculate a position of a first of said virtual bone fragments with respect to a second of said virtual implants and allow said user to align ("ausrichten") said first and second bone fragments with respect to each other, adapted to generate relative position data as a function of said calculated position, and adapted to send said relative position data to said display.

1.2 From claim 2 it becomes clear that such "calculating a position" comprises determining how well virtual computer objects fit along a curve. The computer of D1 is capable of displaying such a fit and thus implicitly also capable of calculating the position of the virtual objects.

1.3 It would be an obvious modification for the skilled person, to make the system of D1 suitable for rearranging and aligning multiple virtual implants in stead of bone

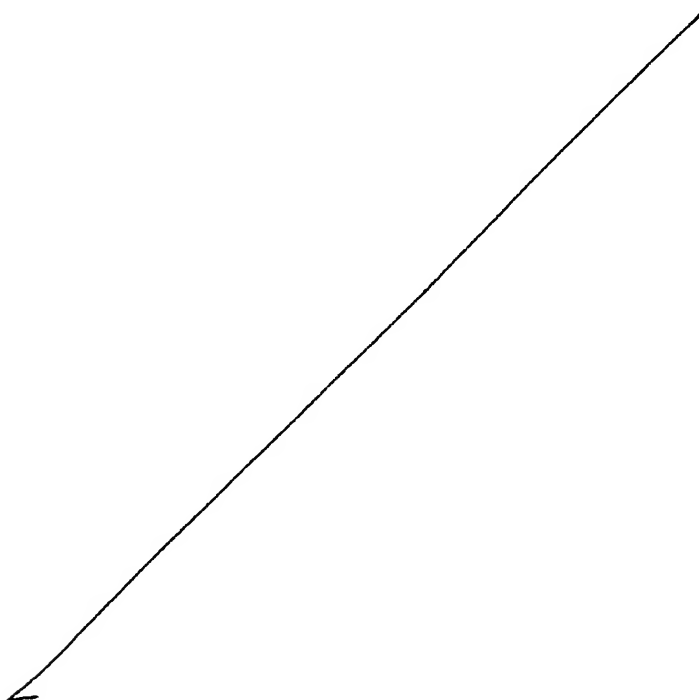
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fragments. Such systems with databases with virtual implants that can be rearranged on a display are well known in the art, see for instance **US-A-20020038085 (D2)**, page 1, paragraph 0011. Thus he would end up with a system as claimed in claim 1 without using any inventive skill.

1.3 Therefore, the subject-matter of claim 1 lacks inventive step. The computer program of D1 is also capable of executing the alignment program for implants in stead of bone fragments, therefore independent claims 25 and 26 also lack inventive step.

1.4 Dependent claims 2-13 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step since these features are either already known from D1 or D2 or they merely are minor modifications of the systems of D1 or D2.



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WHAT IS CLAIMED IS:

1. An apparatus for planning a surgery, the apparatus comprising:
 - a display for an image representing a patient's anatomy;
 - a database of virtual implants from which a user selects;
 - a tool for said user to manipulate in order to select said virtual implants from said database and place said virtual implants in said image at desired locations; and
 - a positioning module adapted to calculating a position of a first of said virtual implants with respect to a second of said virtual implants and allow said user to align said first and second virtual implants with respect to each other, adapted to generating relative position data as a function of said calculated position, and adapted to sending said relative position data to said display.
2. An apparatus as claimed in claim 1, wherein said calculating a position comprises determining how well said virtual implants fit along a curve representing an interconnecting member for said virtual implants.
3. An apparatus as claimed in claim 1, wherein said surgery is a spinal surgery, said virtual implants are at least two spinal implants, and said positioning module is for aligning said at least two spinal implants along a curve representing an interconnecting member for said spinal implants.
4. An apparatus as claimed in claims 1, 2 or 3, wherein said tool allows said user to input a desired relative position of said first virtual implant with respect to said second virtual implant, and said positioning module updates a position of at least one of said first virtual implant and said second virtual implant as a function of said desired relative position.

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23. A method as claimed in claim 14, wherein said providing an image comprises providing a fluoroscopic image.

24. A method as claimed in claim 23, wherein said placing said at least two spinal implants comprises updating said fluoroscopic image after each of said at least two spinal implants has been placed.

25. A computer readable memory for storing programmable instructions for use in the execution in a computer of the method of any one of claims 14 to 24.

26. A computer data signal embodied in a carrier wave comprising data resulting from a positioning module adapted to calculating a position of a first virtual implant with respect to a second virtual implant and allow a user to align said first and second virtual implants with respect to each other, adapted to generating relative position data as a function of said calculated position, and adapted to sending said relative position data to a display.